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Attorney Docket No. 59573 (46865)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Heegaard, et al.

CONF. NO.: 5193

APPLN SERIAL NO.: 10/623,150

ART UNIT: 1632

FILED: July 18, 2003

EXAMINER: Not yet assigned

FOR: METHOD FOR SCREENING COMPOUNDS FOR ACTIVITY IN TREATING AN
OSTEOCIASST RELATED BONE DISEASE

CERTIFICATE OF MAILING

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INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §§1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner.

I. LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION

The patents, publications or other information submitted for consideration by the Office are listed on PTO-1449, attached hereto.

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II. COPIES

a. ☒ Submitted herewith is a legible copy of (i) each U.S and foreign patent; (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed.

III. CONCISE EXPLANATION OF THE RELEVANCE
(check at least one box)

a. ☒ Except as may be indicated below in (b), all of the patents, publications or other information are in the English language or were cited in a PCT Search Report.

b. ☐ A concise explanation of the relevance of all patents, publications or other information listed that is not in the English language is as follows:

c. ☐ The following additional information is provided for the Examiner's consideration:

FEES

IV. THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(b)
(check one box)

a. ☐ within three months of the filing date of a national application (37 C.F.R. § 1.97(b) (1)). No fee or certification is required.

b. ☐ within three months of the date of entry of the national stage as set forth in §1.491 in an international application (37 C.F.R. § 1.97(b) (2)). No fee or certification is required.

c. ☒ before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b) (3)). No fee or certification is required. In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the certification under 37 C.F.R. § 1.97(e) below, or, if no certification has been made, charge our deposit account a fee in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).

V. THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(c):
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a. _____ before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c) (1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c) (2)).

b. ☒ No certification; therefore, a fee in the amount of \$180.00 is required by 37 C.F.R. § 1.17(p).

or

c. _____ See the certification below. No fee is required.

VI. CERTIFICATION UNDER 37 C.F.R. § 1.97(e)
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The undersigned hereby certified that

a. ☒ each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application, or

b. _____ no item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application or, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

c. _____ some of the items of information were cited in a communication from a foreign Patent Office. As to this information, the undersigned certifies that each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby certifies that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application or, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

VII. THIS IDS IS BEING FILED UNDER 37 C.F.R. §1.97(d)

- a. ☐ after the mailing date of a Final Rejection or Notice of Allowance but before the payment of the Issue Fee, and the requisite Certification, petition, and petition fee are included herein.
- b. ☐ after the mailing date of a Final Office Action under 37 C.F.R. §1.113
- c. ☐ see certificate above
- d. ☒ a fee in the amount of \$180.00 is required by 37 CFR §1.17(p)
- e. ☐ applicant hereby petitions that this Information Disclosure Statement is considered in accordance with 37 C.F.R. §1.97(d).

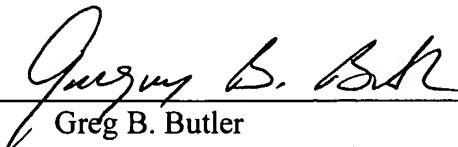
☒ Enclosed is a check in the amount of \$180.00 for the above-indicated fee. Should any further fee be associated with the submission of this Information Disclosure Statement, the Commissioner is authorized to charge our Deposit Account No. 04-1105.

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If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule (with a petition, if necessary) and charge the appropriate fee to Deposit Account No. 04-1105.

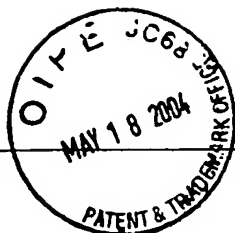
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FORM PTO-1449		DOCKET NO: 59573 (46865)	SERIAL NO.: 10/623,150
INFORMATION DISCLOSURE STATEMENT		APPLICANT(S): Heegaard, et al.	
		FILING DATE: July 18, 2003	GROUP NO.: 1632
OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)			
1	C1	Hartinger, et al., "An Anion Binding Site That Regulates the Glutamate Transporter of Synaptic Vesicles," Journal of Biological Chemistry, Vol. 268, No. 31, pp. 23122-23127, 1993.	
2	C2	Ratcliff, et al., "Production of a Severe Cystic Fibrosis Mutation in Mice by Gene Targeting, Nature Genetics," Vol. 4, pp. 35-41, 1993.	
3	C3	Vincent, et al., "Antisense Suppression of Potassium Channel Expression Demonstrates Its Role in Maturation of the Action Potential, Journal of Neuroscience," Vol. 20, pp. 6087-6094, 2000.	
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6	C6	Clarke, et al., "Defective Epithelial Chloride Transport in a Gene-Targeted Mouse Model of Cystic Fibrosis," Science, Vol. 257, pp. 1125-1128, 1992.	
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8	C8	Maycox, et al., "Glutamate Uptake by Brain Synaptic Vesicles," Journal of Biological Chemistry, Vol. 263, pp. 15423-15428, 1988.	
9	C9	Piwon, et al., "CIC-5 Cl-Channel Disruption Impairs Endocytosis in a Mouse Model for Dent's Disease," Nature, Vol. 408, pp. 369-373, 2000.	
10	C10	Schaertl, et al., "A Novel and Robust Homogeneous Fluorescence-Based Assay Using Nanoparticles for Pharmaceutical Screening and Diagnosis," Journal of Biomolecular Screening, Vol. 5, pp 227-237, 2000.	
11	C11	Yamamoto, et al., "Characterization of Renal Chloride Channel (CLCN5) Mutations in Dent's Disease," Journal of the American Society of Nephrology, Vol. 11, pp. 1460-1468, 2000.	
12	C12	Sun, et al., "CD38/ADP-Ribosyl Cyclase: A New Role in the Regulation of Osteoclastic Bone Resorption," Journal of Cell Biology, Vol., 146, pp. 1161-1171, 1999.	
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14	C14	Kawasaki, et al., "Cloning and Expression of a Protein Kinase C-Regulated Chloride Channel Abundantly Expressed in Rat Brain Neuronal Cells," Neuron, Vol. 12, pp. 597-604, 1994.	
15	C15	Thomas-Reetz, et al., "A γ -Aminobutyric Acid Transporter Driven by a Proton Pump is Present in Synaptic-Like Microvesicles of Pancreatic β -Cells," Proceedings of the National Academy of Sciences USA, Vol. 90, pp. 5317-5321, 1993.	
16	C16	Overly, et al., "Quantitative Measurement of Intraorganelle pH in the Endosomal-Lysosomal Pathway in Neurons by Using Ratiometric Imaging with Pyranine," Proceedings of the National Academy of Sciences USA, Vol. 92, pp. 3156-3160, 1995.	
17	C17	Xia, et al., "Localization of Rat Cathepsin K in Osteoclasts and Resorption Pits: Inhibition of Bone Resorption and Cathepsin K-Activity by Peptidyl Vinyl Sulfones," Biological Chemistry, Vol. 380, pp. 679-687, 1999.	
18	C18	Yeager, et al., "Constructing Immortalized Human Cell Lines," Current Opinion in Biotechnology, Vol. 10, pp. 465-469, 1999.	
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24	C24	Frostell-Karlsson, et al., "Biosensor Analysis of the Interaction Between Immobilized Human Serum Albumin and Drug Compounds for Prediction of Human Serum Albumin Binding Levels," Journal of Medical Chemistry, Vol. 43, pp. 1986-1992, 2000.		
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26	C26	Llopis, et al., "Measurement of Cytosolic, Mitochondrial, and Golgi pH in Single Living Cells with Green Fluorescent Proteins," Proceedings of the National Academy of Sciences USA, Vol. 95, pp. 6803-6808, 1998.		
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29	C29	Williams, "Biotechnology Match Making: Screening Orphan Ligands and Receptors," Current Opinion in Biotechnology, Vol. 11, p. 42-46, 2000.		
30	C30	Beerheide, et al., "Potential Drugs Against Cervical Cancer: Zinc-Ejecting Inhibitors of the Human Papillomavirus Type 16 E6 Oncoprotein," Journal of the National Cancer Institute, Vol. 91, pp. 1211-1220, 1999.		
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32	C32	Deckert, et al., "Development and Validation of an IL-6 Immuno-Receptor Assay Based on Surface Plasmon Resonance," Journal of Pharmaceutical and Biomedical Analysis, Vol. 23, pp. 403-412, 2000.		
33	C33	Shioi, et al., "Glutamate Uptake Into Synaptic Vesicles of Bovine Cerebral Cortex and Electrochemical Potential Difference of Proton Across the Membrane," Biochemistry Journal, Vol. 258, pp. 499-504, 1989.		
34	C34	Kubisch, et al., CIC-1 Chloride Channel Mutations in Myotonia Congenita: Variable Penetrance of Mutations Shifting the Voltage Dependence," Human Molecular Genetics, Vol. 7, pp. 1753-1760, 1998.		
35	C35	Lorenz, et al., "Genomic Organization of the Human Muscle Chloride Channel CIC-1 and Analysis of Novel Mutations Leading to Becker-Type Myotonia," Human Molecular Genetics, Vol. 3, pp. 941-946, 1994.		
36	C36	Tycko, et al., "Rapid Acidification of Endocytic Vesicles Containing α_2 -Macroglobulin," Cell, Vol. 28, pp. 643-651, 1982.		
37	C37	Boyde, et al., "Resorption of Dentine by Isolated Osteoclasts <i>in vitro</i> ," British Dental Journal, Vol. 156, pp. 216-220, 1984.		
38	C38	Chapman, et al., "Retrieval of TGN Proteins From the Cell Surface Requires Endosomal Acidification," The EMBO Journal, Vol. 13, pp. 2305-2312, 1994.		
39	C39	Katakura, et al., "Immortalization by Gene Transfection," Methods in Cell Biology, Vol. 57, pp 69-91, 1998.		
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43	C43	Dorin, et al., "Cystic Fibrosis in the Mouse by Targeted Insertional Mutagenesis," Nature, Vol. 359, pp. 211-215, 1992.		
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50	C50	Leconte, et al., "Impairment of Rod cGMP-Gated Channel α -Subunit Expression Leads to Photoreceptor and Bipolar Cell Degeneration," <i>Investigative Ophthalmology & Visual Science</i> , Vol. 41, pp. 917-926, 2000.		
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52	C52	Brenner, et al., "Vasoregulation by the β 1 Subunit of the Calcium-Activated Potassium Channel," <i>Nature</i> , Vol. 407, pp. 870-876, 2000.		
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54	C54	Inoue, et al., "Visualization of Acidic Compartments in Cultured Osteoclasts by Use of an Acidotrophic Amine as a Marker for Low pH," <i>Cell Tissue Research</i> , Vol. 298, pp. 527-537, 1999.		
55	C55	Piwon, et al., "CIC-5 Cl ⁻ -Channel Disruption Impairs Endocytosis in a Mouse Model for Dent's Disease," <i>Nature</i> , Vol. 408, pp. 369-373, 2000.		
56	C56	Pusch, et al., "Mutations in Dominant Human Myotonia Congenita Drastically Alter the Voltage Dependence of the CIC-1 Chloride Channel," <i>Neuron</i> , Vol. 15, pp. 1455-1463, 1995.		
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59	C59	Baron, et al., "Cell-Mediated Extracellular Acidification and Bone Resorption: Evidence for a Low pH in Resorbing Lacunae and Localization of a 100-kD Lysosomal Membrane Protein at the Osteoclast Ruffled Border," <i>Journal of Cell Biology</i> , Vol. 101, pp. 2210-2222, 1985.		
60	C60	Demaurex, et al., "Mechanism of Acification of the <i>trans</i> -Golgi Network (TGN) <i>IN SITU</i> MEASUREMENTS OF pH USING RETREIVAL OF TGN38 AND FURIN FROM THE CELL SURFACE," <i>Journal of Biological Chemistry</i> , Vol. 273, pp. 2044-2051, 1997.		
61	C61	Igarashi, et al., "Functional Characterization of Renal Chloride Channel, CLCN5, Mutations Associated with Dent's Japan Disease," <i>Kidney International</i> , Vol. 54, pp. 1850-1856, 1998.		
62	C62	Failke, "Molecular Mechanisms of Ion Conduction in CIC-Type Chloride Channels: Lessons from Disease-Causing Mutations," <i>Kidney International</i> , Vol. 57, pp. 780-786, 2000.		
63	C63	Kneen, et al., "Green Fluorescent Protein as a Noninvasive Intracellular pH Indicator," <i>Biophysical Journal</i> , Vol. 74, pp. 1591-1599, 1998.		
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65	C65	Lewalle, et al., "Inhibition of P210 Expression in Chronic Myeloid Leukaemia: Oligonucleotides and/or Transduced Antisense Sequences," <i>Leukemia and Lymphoma</i> , Vol. 11, pp. 139-143, 1993.		
66	C66	Marschall, et al., "Inhibition of Gene Expression with Ribozymes," <i>Cellular and Molecular Neurobiology</i> , Vol. 14, pp. 523-538, 1994.		
67	C67	Borsani, et al., "Characterization of Human and Murine Gene (CLCN3) Sharing Similarities to Voltage-Gated Chloride Channels and to a Yeast Integral Membrane Protein," <i>Genomics</i> , Vol. 27, pp. 131-141, 1995.		
68	C68	Siegel, et al., "A Genetically Encoded Optical Probe of Membrane Voltage," <i>Neuron</i> , Vol. 19, pp. 735-741, 1997.		
69	C69	Presley, et al., "The <i>End2</i> Mutation in CHO Cells Slows the Exit of Transferrin Receptors from the Recycling Compartment but Bulk Membrane Recycling Is Unaffected," <i>Journal of Cell Biology</i> , Vol. 122, pp. 1231-1241, 1993.		
70	C70	Steinmeyer, et al., "Multimeric Structure of CIC-1 Chloride Channel Revealed by Mutations in Dominant Myotonia Congenita (Thomsen)," <i>EMBO Journal</i> , Vol. 13, pp. 737-743, 1994.		

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71	C71	Ratcliff, et al., "Disruption of the Cystic Fibrosis Transmembrane Conductance Regulator Gene in Embryonic Stem Cells by Gene Targeting," Transgenic Research, Vol. 1, pp. 177-181, 1992.	
72	C72	Schwappach, et al., "Golgi Localization and Functionally Important Domains in the NH ₂ and COOH Terminus of the Yeast CLC Putative Chloride Channel Geflp," Journal of Biological Chemistry, Vol. 273, pp. 15110-15118, 1998.	
73	C73	Liu, et al., "Ribozyme Ablation Demonstrates That the Cardiac Subtype of the Voltage-Sensitive Calcium Channel Is the Molecular Transducer of 1,25-Dihydroxyvitamin D ₃ -Stimulated Calcium Influx in Osteoblastic Cells," Journal of Biological Chemistry, Vol. 275, pp. 8711-8718, 2000.	
74	C74	Hell, et al., "Energy Dependence and Functional Reconstitution of the γ -Aminobutyric Acid Carrier from Synaptic Vesicles," Journal of Biological Chemistry, Vol. 265, pp. 2111-2117, 1990.	
75	C75	Matsumura, et al., "Overt Nephrogenic Diabetes Insipidus in Mice Lacking the CLC-K1 Chloride Channel," Nature Genetics, Vol. 21, pp. 95-98, 1999.	
76	C76	Clague, et al., "Vacuolar ATPase Activity Is Required for Endosomal Carrier Vesicle Formation," Journal of Biological Chemistry, Vol. 269, pp. 21-24, 1994.	
77	C77	Laitala-Leinonen, et al., "Inhibition of Intravacuolar Acidification by Antisense RNA Decreases Osteoclast Differentiation and Bone Resorption In Vitro," Journal of Cell Science, Vol. 112, pp. 3657-3666, 1999.	
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81	C81	Lee, et al., "Targeted Disruption of the <i>Kulqt1</i> Gene Causes Deafness and Gastric Hyperplasia in Mice," Journal of Clinical Investigation, Vol. 106, pp. 1447-1455, 2000.	
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84	C84	Brussaard, "Antisense Oligonucleotides Induce Functional Deletion of Ligand Gated Ion Channels in Cultured Neurons and Brain Explants," Journal of Neuroscience Methods, Vol. 71, pp. 55-64, 1997.	
85	C85	Friedrich, et al., "Mutational Analysis Demonstrates That CIC-4 and CIC-5 Directly Mediate Plasma Membrane Currents," Journal of Biological Chemistry, Vol. 27, pp. 896-902, 1999.	
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87	C87	Schapiro, et al., "Determinants of the pH of the Golgi Complex," Journal of Biological Chemistry, Vol. 275, pp. 21025-21032, 2000.	
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89	C89	Sterrer, et al., "Fluorescence Correlation Spectroscopy (FCS) - A Highly Sensitive Method to Analyze Drug/Target Interactions," Journal of Receptor & Signal Transduction Research, Vol. 17, pp. 511-520, 1997.	
90	C90	Kornak, et al., "Complete Genomic Structure of the CLCN6 and CLCN7 Putative Chloride Channel Genes," Biochimica et Biophysica Acta, Vol. 1447, pp. 100-106, 1999.	
91	C91	Chambers, et al., "Resorption of Bone by Isolated Rabbit Osteoclasts," Journal of Cell Science, Vol. 66, pp. 383-399, 1984.	
92	C92	Vandewalle, "Immortalized Kidney Cells Derived from Transgenic Mice Harboring L-Type Pyruvate Kinase and Vimentin Promoters," Experimental Nephrology, Vol. 7, pp. 386-393, 1999.	
93	C93	Gökhan, et al., "Generation and Regulation of Developing Immortalized Neural Cell Lines," Methods, Vol. 16, pp. 345-358, 1998.	

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94	C94	Okazaki, et al., "Thiazolidinediones Inhibit Osteoclast-Like Cell Formation and Bone Resorption <i>in Vitro</i> ," Endocrinology, Vol. 140, pp. 5060-5065, 1999.	
95	C95	Luyckx, et al., "Diet-Dependent Hypercalciuria in Transgenic Mice with Reduced CLC5 Chloride Channel Expression," PNAS, Vol. 96, pp. 12174-12179, 1999.	
EXAMINER:			DATE: